

Notice of Allowability**Application No.**

10/676,872

Applicant(s)

FOMOVSKAIA ET AL.

Examiner

CYNTHIA B. WILDER

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to 9/27/2008.
2. ☒ The allowed claim(s) is/are 4-8,12-14,16 and 27-58.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date ____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

NOTICE OF ALLOWANCE

1. Applicant's amendment filed 6/27/2008 is acknowledged. Claims 4-8, 12-14, 16 and 37-58 are deemed in condition for allowance. Accordingly, the prior art rejections under 35 USC 103(a) are withdrawn.

Examiner's Amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kathryn Piffat on October 24, 2008.

The application has been amended as follows:

(a). The claim 4 was deleted and replaced with the following:

---4. A kit for indicating the presence of nucleic acid in a sample, the kit comprising:

a. a dry substrate for lysing cells and purifying nucleic acid therefrom, said dry substrate consisting of:

i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and

ii. a coating sorbed to the solid matrix, wherein the coating comprises a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate, and

b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon.---

(b). The claim 12 was deleted and replaced with the following:

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---12. A kit for purifying nucleic acid comprising:

- a. a dry substrate comprising:
 - i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and
 - ii. a coating sorbed to the solid matrix, wherein the coating comprises a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate, and
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(c). The claim 16 was deleted and replaced with the following:

---16. A blood card for labeling blood transfusion bags comprising:

- a. a dry substrate comprising a solid matrix selected from the group consisting of nitrocellulose, carboxymethylcellulose, polyester, polyamide, polytetrafluoroethylene and porous ceramics, wherein the solid matrix further comprises a chemical coating sorbed to the solid matrix, the chemical coating comprising:
 - i. a weak base;
 - ii. a chelating agent; and
 - iii. a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate; and
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(d). In the claims 39, 43 and 50 at line 2, the limitation "of from about" was deleted and replaced with ---of at least---.

(e). The claim 46 was deleted and replaced with the following:

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---46. A kit for labeling blood transfusion bags comprising:

- a. a dry substrate comprising a solid matrix selected from the group consisting of nitrocellulose, carboxymethylcellulose, polyester, polyamide, polytetrafluoroethylene and porous ceramics, the solid matrix being coated with a chemical coating sorbed to the solid matrix, the chemical coating comprising a weak base, a chelating agent, and a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate;
- b. an indicator which detects the presence of nucleic acid, wherein the nucleic acid is maintained on the solid matrix, the indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
- c. an integrity maintenance means which reduces degradation or loss of the matrix or the nucleic acid.---

(f). The claim 47 was deleted and replaced with the following:

---47. A kit for purifying nucleic acid comprising:

- a. a dry substrate for lysing cells and purifying nucleic acid comprising a solid matrix comprising nitrocellulose, the solid matrix being coated with a chemical coating sorbed to the solid matrix, the chemical coating comprising:
 - i. a weak base;
 - ii. a chelating agent; and
 - iii. a cellular lysis reagent comprising an anionic surfactant or detergent at a concentration of at least 5% which induces cellular lysis and releases or stabilizes the nucleic acid onto the dry substrate; and
- b. an indicator which detects the presence of nucleic acid, wherein:
 - i. the indicator comprises an external substance which generates a signal and detects the presence of the nucleic acid immobilized thereon; and
 - ii. the indicator comprises a polyethyleneimine conjugate or an enzyme-linked immunosorbant assay (ELISA) reagent.---

(g). In the claim 53, the limitation ---reagent--- was inserted after "(ELISA)" at the end of the sentence.

3. The following is an examiner's statement of reasons for allowance:

Applicant's arguments and the Declaration under 37 CFR 1.132 filed October 27,

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2007 necessitated withdrawal of the prior art rejections under 35 USC 103(a). The arguments provide sufficient evidence of inoperability of the dry solid matrix of the prior art when using a lysis reagent above 2%. No prior art was found teaching or suggesting a dry solid matrix comprising a chemical coating, wherein said chemical coating comprises a lysis reagent in the concentration of at least 5% and an indicator comprising an external substance which generates a signal and detects the presence of the nucleic acid immobilized on the dry solid matrix. Accordingly, the claims 4-8, 12-14, 16 and 37-58 are deemed novel and unobvious.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637

/CBW/